DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

94186a

AUG 1 2003

WARNING LETTER

VIA Federal Express

Ref: OC: I1-1947

Mr. T. K. Cheung
General Manager
Keitsen Technology (Shenzhen) Co., Ltd.
Qiaotou Industrial Estate
Fuyony Town, Baoan District
Shenzhen City 518103
CHINA

Dear Mr. Cheung:

The Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), has completed its review of the laboratory test conducted by FDA's Winchester Engineering and Analytical Center (WEAC) of an Ultrex brand microwave oven Model 14075, serial number 5576, manufactured in September 2002. This microwave oven sample was voluntarily submitted by your company to WEAC for comprehensive laboratory analysis of compliance with the United States (U.S.) Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10, and other applicable regulations under the U.S. Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C – Electronic Product Radiation Control. The WEAC laboratory completed its analysis on June 12, 2003, and a copy of the laboratory report is enclosed for your information.

We have determined that this microwave oven and other similarly designed ovens fail to comply with 21 CFR 1030.10 and other applicable regulations as follows:

1. 21 CFR 1030.10(c)(2)(v) - The oven failed to comply with the requirements that the secondary safety interlock prevent microwave emission in excess of 5 mW/cm^2. The WEAC analyst reported that the oven emitted 13.5 mW/cm^2 when the door handle was pulled straight back with just the secondary interlock operating. A separate check by another analyst reported that the oven emitted approximately 9.3 mW/cm^2, when the door handle was pulled straight back with just the secondary interlock operating.

2. 21 CFR 1030.10(c)(2)(iv) – It was possible to insert a straight wire (0.035 inch in diameter) into the oven cavity through the back left grill, through a set of vent holes on the side of the cavity. This would be expected to cause the oven to leak microwave radiation greater than 5.0 mW/cm^2, in violation of the Federal Performance Standard.

3. 21 CFR 1010.2, 1010.3 and 1030.10(c)(6) - The identification, certification, user caution and service caution labels were not permanently affixed to the microwave oven. The labels were not properly applied on the surface and, therefore, could be peeled easily from the oven.

4. 21 CFR 1030.10(c)(4)(iii) - The user instructions contain several discrepancies in wording from that required by the Federal Performance Standard. In your user manual, the title to the precautions that should read "PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY," omitted the words "POSSIBLE EXPOSURE TO." Where the instructions should have said "It is important not to defeat or tamper with the safety interlocks," the word "the" was omitted between the words "with" and "safety." And where the instructions should have said "It is particularly important that the oven door close properly and that there is no damage to the: (1) Door (bent)," the word "closes" was substituted for the word "close", and the word "dent" was substituted for the word "bent."

5. 21 CFR 1002.10 – CDRH never received a product report or supplement identifying the Ultrex Model 14075 as a new model that would be imported by Innova, Inc. The requirement that a report or supplement be submitted prior to the introduction of the product into interstate commerce enables FDA to determine the radiation safety of products that are intended for U.S. commerce.

Sections 538(a)(1) and (a)(5) of the Act [21 U.S.C. section 360oo(a)(1) and (a)(5)] prohibit any manufacturer from certifying or introducing into U.S. commerce microwave ovens which do not comply with an applicable standard, and any person from failing to issue a required certification. Section 538(a)(4) [U.S.C. section 360oo(a)(4)] prohibits any person from failing to establish and maintain required records or to submit required reports. Under the Act, an importer is also considered to be a manufacturer (Section 531(3) [21 U.S.C. section 360hh(3)]).

Under Section 536(a) of the Act [21 U.S.C. section 360mm(a)], FDA may refuse entry or importation into U.S. commerce of any electronic product if it appears that the product fails to comply with the applicable standards. Therefore, microwave ovens manufactured by Keitsen Technology (Shenzhen) Co., Ltd. may be detained without physical examination upon entry into the U.S. until the violations cited in this letter have been corrected or resolved.

In accordance with 21 CFR 1003.11(b), you must notify us of the total number and location of Ultrex brand Model 14075 (and any similarly designed ovens likely to have similar noncompliances) produced (including identification of all models and brands involved) and the approximate number that have left the place of manufacture for U.S. commerce. If there are other products with similar violations, you are to include them in your notification to us. In addition, if the product distribution was confined to specific geographical areas of the U.S., please specify those areas. You must respond in writing within 15 days of receipt of this letter. Your response should pursue one of the options listed below:

1. Refutation – You may submit your views and evidence in accordance with 21 CFR 1003.11(a)(3) to establish that the alleged noncompliances do not exist, do not relate to the safety of the product, or are directly attributable to user abuse or lack of maintenance. Should you choose to refute the allegations of noncompliance, you will have an opportunity to request a hearing under 21 CFR Part 16.

2. Exemption Request – If you do not refute the alleged noncompliances, in accordance with 21 CFR 1003.30, you may request an exemption from the requirements of user and dealer/distributor notification found in 21 CFR 1003.10(b). You must include the grounds upon which such exemption is requested. Please see 21 CFR 1003.31 for further information on what constitutes reasonable grounds for an exemption. Also indicate all models and brands that are to be covered by the exemption, along with the number produced and dates of production.

3. Purchaser Notification and Corrective Action – If you neither refute the alleged noncompliances nor request an exemption, then you will be required to (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a corrective action plan (CAP) showing how you will fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products at no charge to the user.

    a. Notification Letter – Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to this office. It is recommended that you submit a draft of any letters to us for review and concurrence prior to mailing. Please submit such drafts with your response to this letter, because under 21 CFR 1003.11(c), you will have only 14 days to furnish the notification to purchasers and dealers/distributors once we direct you to begin notification.

    b. Corrective Action Plan – Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, and 1004.4. Such a plan must expeditiously correct the noncompliances and must be approved by FDA (see 21 CFR 1004.6).

If you request additional time to investigate the extent of the problem or to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required by 21 CFR 1003.11(c) and 1003.21 to proceed with interim notification to affected persons. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

Failure to respond to this letter or to correct these products in a timely manner can result in regulatory action being initiated by the FDA without further notice. These actions may include, but are not limited to injunction and/or imposition of civil penalties as provided for in Section 539 of the Act [21 U.S.C. section 360pp]. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You are reminded that the above items relate to products already introduced into U.S. commerce. You should address matters concerning current production units under separate cover. You must supplement your product report(s) or quality control aspect report to identify steps you are taking to assure that present production meets all applicable Federal requirements. This supplement must be received prior to any further introduction of Ultrex brand Model 14075 (and any similarly designed ovens likely to have similar noncompliances) into U.S. commerce, as it is unlawful to introduce into U.S. commerce any electronic product which does not comply with an applicable standard (Section 538(a)(1) [21 U.S.C. section 360oo(a)(1)]).

A copy of this letter will be posted on the FDA's world wide web home page under Warning Letters: http://www.fda.gov.

In your response, please reference this letter and our case number 11-1947. Mail it to:

Director
Office of Compliance (HFZ-342)
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, Maryland 20850.

If you have further questions on these requirements, please contact Mr. George W. Kraus, Jr. of the Electronic Products Branch at 301-594-4654, or by facsimile at 301-594-4672, or by electronic mail: gwk@cdrh.fda.gov.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: WEAC Test Results – Sample No. 196595

CC:

Mr. Lewis A. Mendelson
Vice President
Innova, Inc.
409 West 76th Street
Davenport, Iowa 52806